

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
6 June 2002 (06.06.2002)

PCT

(10) International Publication Number
WO 02/043660 A3

(51) International Patent Classification: A61K 39/395,
39/42, 39/00, 39/155, C12Q 1/70

(21) International Application Number: PCT/US01/44807

(22) International Filing Date:
28 November 2001 (28.11.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
09/724,396 28 November 2000 (28.11.2000) US
09/724,531 28 November 2000 (28.11.2000) US

(71) Applicant: MEDIUMMUNE, INC [US/US]; 35 West
Watkins Mill Road, Gaithersburg, MD 20878 (US).

(72) Inventors: YOUNG, James, F.; 18309 Mockingbird
Lane, Darnestown, MD 20874 (US). KOENIG, Scott;
10901 Ralson Road, Rockville, MD 20852 (US). JOHN-
SON, Leslie, S.; 20147 Laurel Hill Way, Germantown,
MD 20874 (US).

(74) Agent: INSOGNA, Anthony, M.; Pennie & Edmonds
LLP, 1155 Avenue of the Americas, New York, NY 10036
(US).

(81) Designated States (*national*): AE, AG, AI, AM, AT, AU,
AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU,
CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH,
GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC,
LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW,
MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SD, SE, SG,
SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, UZ, VN, YU,
ZA, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM,
KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW),
Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM),
European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR,
GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent
(BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR,
NE, SN, TD, TG).

Published:
— with international search report

(88) Date of publication of the international search report:
19 June 2003

For two-letter codes and other abbreviations, refer to the "Guid-
ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.



WO 02/043660 A3

(54) Title: METHODS OF ADMINISTERING/DOSING ANTI-RSV ANTIBODIES FOR PROPHYLAXIS AND TREATMENT

(57) Abstract: The present invention encompasses novel antibodies and fragments thereof which immunospecifically bind to one or more RSV antigens and compositions comprising said antibody fragments. The present invention encompasses methods preventing respiratory syncytial virus (RSV) infection in a human, comprising administering to said human a prophylactically effective amount of one or more antibodies or fragments thereof that immunospecifically bind to one or more RSV antigens, wherein a certain serum titer of said antibodies or antibody fragments is achieved in said human subject. The present invention also encompasses methods for treating or ameliorating symptoms associated with a RSV infection in a human, comprising administering to said human a therapeutically effective amount of one or more antibodies or fragments thereof that immunospecifically bind to one or more RSV antigens, wherein a certain serum titer of said antibodies or antibody fragments is achieved in said human subject. The present invention further encompasses compositions comprising antibodies or fragments thereof that immunospecifically bind to a SRV antigen, and methods using said compositions for detection or diagnosis a RSV infection.

BEST AVAILABLE COPY

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/44807

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61K 39/395, 39/42, 39/00, 39/155; C12Q 1/70
US CL : 424/130.1, 133.1, 147.1, 184.1, 211.1; 435/5

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 424/130.1, 133.1, 147.1, 184.1, 211.1; 435/5

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X.T	HACKING, D. et al. Respiratory Syncytial Virus - Viral Biology and the Host Response. Journal of Infection. October 2002, Vol. 45, pages 18-24, especially abstract.	96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

Special categories of cited documents:	
* "A" document defining the general state of the art which is not considered to be of particular relevance	* "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
* "E" earlier application or patent published on or after the international filing date	* "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
* "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	* "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
* "O" document referring to an oral disclosure, use, exhibition or other means	* "&" document member of the same patent family
* "P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search 25 October 2002 (25.10.2002)	Date of mailing of the international search report 27 MAR 2003
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703)305-3230	Authorized officer Felicia D. Roberts for Stacy S. Brown Telephone No. 703-308-0196

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US01/44807

Box I Observations where certain claims were found unsearchable (Continuation of Item 1 of first sheet)

This international report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claim Nos.:
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claim Nos.:
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:
3. ☐ Claim Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of Item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:
Please See Continuation Sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☒ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.: Please See Continuation Sheet
4. ☐ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

BOX II. OBSERVATIONS WHERE UNITY OF INVENTION IS LACKING

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be searched, the appropriate additional search fees must be paid.

Note that all claims reciting the trademark SYNAGIS and HL-SYNAGIS will be searched only in part regarding the antibodies that are non-SYNAGIS, or excluded from the search (claims 140, 141, 162-169, 186-191, 197, 201 and 218-223). SYNAGIS and HL-SYNAGIS antibodies cannot be searched because they are trademarks, whose exact amino acid sequences are not disclosed in this application and can be changed by the owner. Claims in Group 43 will only be searched in part based on a text name search since amino acid sequences have not been provided.

Group 1, claim(s) 1, 37, 38, 40, 56, 65-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200, 202-206 and 208-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VH domain* selected from the group consisting of 14 sequences. The 14 sequences represent 14 special technical features.

Group 2, claim(s) 2, 37, 39, 41, 57, 65-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200, 202-206 and 208-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VL domain* selected from the group consisting of 23 sequences. The 23 sequences represent 23 special technical features.

Group 3, claim(s) 3, 36, 37, 42, 58, 65-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-206 and 208-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VH and VL domain* selected from the group consisting of 14 and 23 sequences, respectively, for a total of 322 possible combinations. The 322 sequence combinations represent 322 special technical features.

Group 4, claim(s) 4, 37, 43, 44, 59, 65-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VH CDR1 domain* selected from the group consisting of 3 sequences. The 3 sequences represent 3 special technical features.

Group 5, claim(s) 5, 37, 45, 46, 60, 65-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VH CDR2 domain* selected from the group consisting of 16 sequences. The 16 sequences represent 16 special technical features.

Group 6, claim(s) 6, 37, 47, 48, 53, 54, 61, 65-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VH CDR3 domain* selected from the group consisting of 8 sequences. The 8 sequences represent 8 special technical features.

Group 7, claim(s) 7, 37, 49, 50, 62, 65-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VL CDR1 domain* selected from the group consisting of 80 sequences. The 80 sequences represent 80 special technical features.

Group 8, claim(s) 8, 37, 51, 52, 63, 65-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VL CDR2 domain* selected from the group consisting of 58 sequences. The 58 sequences represent 58 special technical features.

INTERNATIONAL SEARCH REPORT

Group 9, claim(s) 9, 37, 53, 54, 64-85, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody, nucleic acid encoding the antibody, vectors, host cells, methods of producing, pharmaceuticals and methods of treating, wherein the antibody has a *VL CDR3* domain selected from the group consisting of 3 sequences. The 3 sequences represent 3 special technical features.

Group 10, claim(s) 10, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody comprises *VH CDR1* and *VH CDR2*, selected from the groups consisting of 3 and 16 sequences, respectively, for a total of 48 possible sequence combinations. The 48 combinations represent 48 distinct inventions.

Group 11, claim(s) 11, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody comprises *VH CDR1* and *VH CDR3*, selected from the groups consisting of 3 and 8 sequences, respectively, for a total of 24 possible sequence combinations. The 24 combinations represent 24 special technical features.

Group 12, claim(s) 12, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody comprises *VH CDR1*, *VH CDR2* and *VH CDR3*, selected from the groups consisting of 3, 16 and 8 sequences, respectively, for a total of 384 possible sequence combinations. The 384 combinations represent 384 special technical features.

Group 13, claim(s) 13, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody comprises *VH CDR1* and *VL CDR1*, selected from the groups consisting of 3 and 80 sequences, respectively, for a total of 240 possible sequence combinations. The 240 combinations represent 240 special technical features.

Group 14, claim(s) 14, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody comprises *VH CDR1* and *VL CDR2*, selected from the groups consisting of 3 and 58 sequences, respectively, for a total of 174 possible sequence combinations. The 174 combinations represent 174 special technical features.

Group 15, claim(s) 15, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody comprises *VH CDR1* and *VL CDR3*, selected from the groups consisting of 3 and 3 sequences, respectively, for a total of 9 possible sequence combinations. The 9 combinations represent 9 special technical features.

Group 16, claim(s) 16, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody comprises *VH CDR1* and *VL CDR1*, *VL CDR2* and *VL CDR3*, selected from the groups consisting of 3, 80, 58 and 3 sequences, respectively, for a total of 41,760 possible sequence combinations. The 41,760 combinations represent 41,760 special technical features.

Group 17, claim(s) 17, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claims 10, 11 or 12, and further comprises *VL CDR1* selected from the group consisting of 80 sequences. For the antibodies of claims 10, 11 and 12 with the *VL CDR1*, there are 3840, 1920 and 30,720 possible sequence combinations, respectively. The total number of possible sequence combinations is 36,480. The 36,480 combinations represent 36,480 special technical features.

Group 18, claim(s) 18, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claims 10, 11 or 12, and further comprises *VL CDR2* selected from the group consisting of 58 sequences. For the antibodies of claims 10, 11 and 12 with the *VL CDR2*, there are 2784, 1392 and 22,272 possible sequence combinations, respectively. The total number of possible sequence combinations is 26,448. The 26,448 combinations represent 26,448 special technical features.

Group 19, claim(s) 19, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claims 10, 11 or 12, and further comprises *VL CDR3* selected from the group consisting of 3 sequences. For the antibodies of claims 10, 11 and 12 with the *VL CDR3*, there are 144, 72 and 1152 possible sequence combinations, respectively. The total number of possible sequence combinations is 1,368. The 1,368 combinations represent 1,368 special technical features.

Group 20, claim(s) 20, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claims 10 or 11, and further comprises *VL CDR1*, *VL CDR2* and *VL CDR3*, selected from the groups consisting of 80, 58 and 3 sequences, respectively. For the antibodies of claims 10 or 11 with the *VL CDR1*, *VL CDR2* and *VL CDR3*, there are 668,160 and 334,080 possible sequence combinations, respectively.

INTERNATIONAL SEARCH REPORT

PCT/US01/44807

combinations, respectively. The total number of possible sequence combinations is 1,002,240. The 1,002,240 combinations represent 1,002,240 special technical features.

Group 21, claim(s) 21, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 12, and further comprises *VL CDR1*, *VL CDR2* and *VL CDR3*, selected from the groups consisting of 80, 58 and 3 sequences, respectively. For the antibody of claim 12 with the *VL CDR1*, *VL CDR2* and *VL CDR3*, there are 5,345,280 possible sequence combinations, respectively. The 5,345,280 combinations represent 5,345,280 special technical features.

Group 22, claim(s) 22, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 5, and further comprises *VH CDR3*, selected from the group consisting of 8 sequences. For the antibody of claim 5 with the *VH CDR3*, there are 128 possible sequence combinations. The 128 combinations represent 128 special technical features.

Group 23, claim(s) 23, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 5, and further comprises *VL CDR1*, selected from the group consisting of 80 sequences. For the antibody of claim 5 with the *VL CDR1*, there are 1280 possible sequence combinations. The 1280 combinations represent 1280 special technical features.

Group 24, claim(s) 24, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 5, and further comprises *VL CDR2*, selected from the group consisting of 58 sequences. For the antibody of claim 5 with the *VH CDR2*, there are 928 possible sequence combinations. The 928 combinations represent 928 special technical features.

Group 25, claim(s) 25, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 5, and further comprises *VL CDR3*, selected from the group consisting of 3 sequences. For the antibody of claim 5 with the *VL CDR3*, there are 48 possible sequence combinations. The 48 combinations represent 48 special technical features.

Group 26, claim(s) 26, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claims 5 or 22, and further comprises *VL CDR1*, *VL CDR2* and *VL CDR3*, selected from the groups consisting of 80, 58 and 3 sequences, respectively. For the antibody of claims 5 or 22 with the *VL CDR1*, *VL CDR2* and *VL CDR3*, there are 222,720 and 1,781,760 possible sequence combinations, respectively. The total number of possible sequence combinations is 2,004,480. The 2,004,480 combinations represent 2,004,480 special technical features.

Group 27, claim(s) 27, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 6, and further comprises *VL CDR1*, selected from the group consisting of 80 sequences. For the antibody of claim 6 with the *VL CDR1*, there are 640 possible sequence combinations. The 640 combinations represent 640 special technical features.

Group 28, claim(s) 28, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 6, and further comprises *VL CDR2*, selected from the group consisting of 58 sequences. For the antibody of claim 6 with the *VL CDR2*, there are 464 possible sequence combinations. The 464 combinations represent 464 special technical features.

Group 29, claim(s) 29, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 6, and further comprises *VL CDR3*, selected from the group consisting of 3 sequences. For the antibody of claim 6 with the *VL CDR3*, there are 3 possible sequence combinations. The 24 combinations represent 24 special technical features.

Group 30, claim(s) 30, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 6, and further comprises *VL CDR1*, *VL CDR2* and *VL CDR3*, selected from the groups consisting of 80, 58 and 3 sequences, respectively. For the antibody of claim 6 with the *VL CDR1*, *VL CDR2* and *VL CDR3*, there are 111,360 possible sequence combinations, respectively. The 111,360 combinations represent 111,360 special technical features.

Group 31, claim(s) 31, 33, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 7, and further comprises *VL CDR2*, selected from the group consisting of 58 sequences. For the antibody of claim 7 with the *VL CDR2*, there are 4640 possible sequence combinations. The 4640 combinations represent 4640 special technical features.

INTERNATIONAL SEARCH REPORT

PCT/US01/44807

Group 32, claim(s) 32, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 7, and further comprises *VL CDR3*, selected from the group consisting of 3 sequences. For the antibody of claim 7 with the *VL CDR3*, there are 240 possible sequence combinations. The 240 combinations represent 240 special technical features.

Group 33, claim(s) 34, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 8, and further comprises *VL CDR3*, selected from the group consisting of 3 sequences. For the antibody of claim 8 with the *VL CDR3*, there are 84 possible sequence combinations. The 84 combinations represent 84 special technical features.

Group 34, claim(s) 35, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-216, drawn to an antibody and method of treating with the antibody, wherein the antibody is the antibody of claim 7, and further comprises *VL CDR2* and *VL CDR3*, selected from the groups consisting of 58 and 3 sequences, respectively. For the antibody of claim 7 with the *VL CDR2* and *VL CDR3*, there are 13,920 possible sequence combinations. The 13,920 combinations represent 13,920 special technical features.

Group 35, claim(s) 86 and 88, drawn to a method for detecting a RSV infection using an antibody, wherein the antibody has a *VH domain* selected from the group consisting of 14 sequences. The 14 sequences represent 14 special technical features.

Group 36, claim(s) 87 and 89, drawn to a method for detecting a RSV infection using an antibody, wherein the antibody has a *VL domain* selected from the group consisting of 23 sequences. The 23 sequences represent 23 special technical features.

Group 37, claim(s) 90, drawn to a method for detecting a RSV infection using an antibody, wherein the antibody has a *VH CDR1* selected from the group consisting of 3 sequences. The 3 sequences represent 3 special technical features.

Group 38, claim(s) 91, drawn to a method for detecting a RSV infection using an antibody, wherein the antibody has a *VH CDR2* selected from the group consisting of 16 sequences. The 16 sequences represent 16 special technical features.

Group 39, claim(s) 92, drawn to a method for detecting a RSV infection using an antibody, wherein the antibody has a *VH CDR3* selected from the group consisting of 8 sequences. The 8 sequences represent 8 special technical features.

Group 40, claim(s) 93, drawn to a method for detecting a RSV infection using an antibody, wherein the antibody has a *VL CDR1* selected from the group consisting of 80 sequences. The 80 sequences represent 80 special technical features.

Group 41, claim(s) 94, drawn to a method for detecting a RSV infection using an antibody, wherein the antibody has a *VL CDR2* selected from the group consisting of 58 sequences. The 58 sequences represent 58 special technical features.

Group 42, claim(s) 95, drawn to a method for detecting a RSV infection using an antibody, wherein the antibody has a *VL CDR3* selected from the group consisting of 3 sequences. The 3 sequences represent 3 special technical features.

Group 43, claim(s) 55, 96-139, 142-161, 170-185, 192-196, 198-200, 202-206 and 208-217, drawn to an antibody and method for treating with the antibody, wherein the antibody is selected from the group consisting of 24 antibody names. Lacking evidence to the contrary, the 24 names have different amino acid sequence and encode 24 different antibodies and therefore represent 24 special technical features.

The inventions listed as Groups 1-43 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Groups 1-34 and the numerous sequence combinations thereof comprise different amino acid sequences and therefore lack the same special technical feature. The antibodies used in the methods of Groups 35-42 lack the same special technical feature for the same reason.

Groups 1 and 35 are drawn to antibody/method of treating, and method of detecting, respectively. The antibodies used in both methods comprise the same set of sequences. Groups 1 and 35 lack the same special technical feature because PCT Annex B of Administrative Instructions only allows for one method of use to be joined with the main invention. In the same way, Groups 2 and 36, 4 and 37, 5 and 38, 6 and 39, 7 and 40, 8 and 41, and 9 and 42 lack the same special technical feature.

Collectively, groups 3 and 10-34 lack the same special technical feature with groups 35-42. The antibodies used in the methods of treating (groups 3 and 10-34) and detecting (groups 35-42) are not comprised of the same sets of amino acid sequences.

Groups 1-34 and group 43 lack the same special technical feature because it cannot be determined if the antibodies claimed in group 43 are the same as claimed in groups 1-34. For the same reasons, groups 35-42 and group 43 lack the same special technical feature.

Form PCT/ISA/210 (second sheet) (July 1998)

INTERNATIONAL SEARCH REPORT

PCT/US01/44807

Applicant is invited to clarify the identity of the antibodies. If the antibodies of group 43 are the same as those of groups 1-34, then group 43 will be rejoined appropriately to groups 1-34, but group 43 will not be joined with groups 35-42 because the PCT Annex B of Administrative Instructions only allows for one method of use to be joined with the main invention.

The number of inventions in groups 1-2, 4-9 and 35-43 was calculated by adding the number of different sequences listed in each claim. The number of inventions in groups 3 and 10-34 was calculated by multiplying the number of sequences in one domain by the number in another domain, resulting in the total number of possible combinations between domains. For example, group 3 is drawn to an antibody with a VH domain selected from 14 sequences, and a VL domain selected from 23 sequences. The number of VH sequences was multiplied by the number of VL sequences, resulting in 322 possible combinations of VH and VL domains for group 3. Similar calculations were carried out for groups 10-34. The total number of inventions is the sum of each group's inventions.

If Applicant declines paying additional fees for the search of additional inventions, Group 1 will be searched with respect to the first named sequence, SEQ ID NO: 7. If Applicant pays for additional inventions, groups that have multiple sequences will be searched with respect to the first named sequence, unless otherwise instructed.

Continuation of Box II Item 3:

21, 96-106, 108-121, 123-134, 136-139, 142-143, 146-161, 170-180, 182-185, 192-196, 198-200 and 202-106

Continuation of B. FIELDS SEARCHED Item 3:

EAST, SPTREMBL_19, SWISSPROT_40, PIR-71, A_GENESEQ_032802, ISSUED_PATENTS_AA
search terms: young, koenig, johnson, respiratory syncytial virus, rsv, antibodies, method, treatment, prevention, ameliorate, administer, humanized